



Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

Information Collection Request Title: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys

OMB No. 0906-0014, Revision.

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N-39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys
OMB No. 0906-0014 – Revision.

Abstract: The purpose of the public health system assessment surveys is to inform the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Committee) on states' ability to add newborn screening for particular conditions, including the feasibility, readiness and overall capacity to screen for a new condition.

The Committee was established under Section 1111 of the Public Health Service Act, 42 U.S.C. 300b-10, as amended in the Newborn Screening Saves Lives Reauthorization Act of 2014. The

Committee is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The purpose of the Committee is to provide the Secretary with recommendations, advice, and technical information regarding the most appropriate application of technologies, policies, guidelines, and standards for: (a) effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders; and (b) enhancing the ability of state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders. Specifically, the Committee makes systematic evidence-based recommendations on newborn screening for conditions that have the potential to change the health outcomes for newborns.

The Committee tasks an external workgroup to conduct systematic evidence-based reviews for conditions being considered for addition to the Recommended Uniform Screening Panel, and their corresponding newborn screening test(s), confirmatory test(s), and treatment(s). Reviews also include an analysis of the benefits and harms of newborn screening for a selected condition at a population level and an assessment of state public health newborn screening programs' ability to implement the screening of a new condition.

Need and Proposed Use of the Information: The surveys are administered by the Committee's Evidence Review Group to collect data from state newborn screening programs in the United States. The surveys have been developed to capture the following: (1) readiness of state public health newborn screening programs to expand newborn screening to include the

target condition; (2) specific requirements of screening for a condition that could hinder or facilitate implementation in each state; and (3) estimated timeframes needed for each state to complete major milestones toward full implementation of newborn screening for the condition.

The data gathered informs the Committee on the following: (1) feasibility of implementing population-based screening for the target condition; (2) readiness of state newborn screening programs to adopt screening for the condition; (3) gaps or limitations related to the feasibility or readiness of states to screen for a condition; and (4) areas of technical assistance and resources needed to facilitate screening for conditions with low feasibility or readiness.

HRSA anticipates the following revisions will be made to the surveys: (1) editing and adding response choices as needed, to provide more informative options; (2) revising language throughout the survey to ensure the survey can accommodate different types of conditions that may be nominated; (3) reorder current questions as needed; and (4) add new questions as needed.

Likely Respondents: The respondents to the survey will be state and territorial newborn screening programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining

information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
INITIAL Survey of the Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment ¹	59	1	59	10	590
FOLLOW-UP Survey of the Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment	30 ²	1	30	2	60

Total	89		89		650
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¹The respondents to the survey will be State and territorial newborn screening programs.

²Up to 30 States and/or Territories will be asked to complete a follow-up survey.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

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